DOCKET NO.: 17328 CON3 **PATENT**
ALLE0032-100
Serial No. 10/630,604

REMARKS

Upon entry of the above amendment, claims 1, 4-5, 9, 12-13 and 29-36 will be pending in this application. Amended claims 1, 31, 33 and 36 recite the "outcome" of "alleviating the burn pain", and are fully supported by the specification at, for example, page 44, Example 6. No new matter is added.

As a preliminary matter, Applicant acknowledges the Office Action's rejection of present claims 1, 4, 5, 9, 12, 13 and 28-32 for alleged nonstatutory double patenting over co-pending US Patent Application No. 10/630,206 As this rejection is provisional in nature, Applicant will address this issue in a subsequent response upon indication of otherwise allowable subject matter in the present application.

The Claims Are Definite

Claims 1, 4-5, 9, 12-13 and 28-32 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for lacking essential steps, i.e., the "outcome of the treatment". The amended claims recite the "outcome" step ("alleviating the burn pain") to comply with the Office Action's requirement. Thus, the claims are definite.

Claim 28 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for being the same scope as that of claim 1. Applicant respectfully disagrees because the step of "local" administration of claim 1 has a different scope from the step of "peripheral" administration of claim 28. See, for example, the definitions of "local" and "peripheral" administration on page 25 of the specification. However, solely to facilitate prosecution, Applicant has canceled claim 28 and amended claim 1 to recite the step of "peripheral" administration of claim 28. Thus, the rejection is rendered moot.

DOCKET NO.: 17328 CON3 **PATENT**
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The Claims Are Not Obvious

Claims 1, 4-5, 12-13 and 28 and 29 are rejected under 35 U.S.C. § 103(a) as being obvious over US Patent Publication No. 2001/0036943 (hereinafter "the Coe reference"). Applicant respectfully asserts that the Office Action has not established a *prima facie* case of obviousness with respect to the Coe reference.

In establishing a *prima facie* case of obviousness under 35 U.S.C. §103, it is incumbent upon the Office to provide a reason why one of ordinary skill in the art would have been led to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. Int. 1985). To this end, the requisite motivation **must** stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and **not** from applicant's disclosure. See for example, *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988); and *Ex parte Nesbit*, 25 U.S.P.Q.2d 1817, 1819 (Bd. Pat. App. Int. 1992). In this respect, the following quotation from *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993), is noteworthy:

> Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that "would lead" that individual "to combine the relevant teachings of the references." ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force that would **impel** one skilled in the art to do what the patent applicant has done.

(citations omitted; emphasis added). Significantly, the Office Action identifies no "motivating force" that would "impel" a person of ordinary skill to pick out and combine the specific features randomly identified in the Coe reference to arrive at the present invention.

Generally, the Coe reference discloses a method of treating acute, chronic and/or neuropathic pain and migrane in a mammal by administering a nicotine receptor partial agonist (NRPA) and an analgesic agent (e.g., botulinum toxin). The specification of the Coe reference discloses a long list of NRPAs and a long list of analgesic agents. See, for example, paragraphs [0006] to [0137] of the Coe reference. Also, the Coe reference reports that the combination of NRPA and analgesic agent may be used to treat a number of pain conditions, including burn pain. See paragraph [0271] of the Coe reference.

The Office Action alleges it would be obvious to one of ordinary skill to pick botulinum toxin from the list of analgesic agents, and to pick burn pain from the list of pain conditions because botulinum toxin has been used to treat migraine headache pain and other pain conditions. Specifically, the Office Action states that in view of the

> known properties and the use of botulinum toxin, it is obvious that one of ordinary skill in the art would be able to selectively pick botulinum toxin for use in treating burn pain.

The Office Action, page 5. Respectfully, Applicant asserts that the Coe reference and other prior art knowledge would not impel one of ordinary skill to use a botulinum toxin to alleviate a burn pain, because, for example, the biochemical and neurological mechanisms of a burn pain may be very different from other types of pain. For example, a migraine headache pain primarily results from a vascular dilation, whereas a burn pain primarily results from a necrotic tissue. Since a burn pain has its own etiology, in reading the disclosure of the Coe reference, one would not be motivated, or impelled, to pick botulinum toxin to administer to alleviate a burn pain.

At most, it would be "obvious to try" the administration of a botulinum toxin to alleviate a burn pain. However, "obvious to try" is not the proper standard for obviousness. In *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir., 1988), the court stated, "It is true that this court and its predecessors have repeatedly emphasized that 'obvious to try' is not the standard under § 103." Clearly, the law requires that the prior art is such

DOCKET NO.: 17328 CON3
ALLE0032-100
Serial No. 10/630,604

PATENT

that one of ordinary skill would be impelled from the Coe reference to select a botulinum toxin for alleviating a burn pain, and the Office Action has not provided any showing that one of ordinary skill would be so impelled.

Since the Office Action has not provided any evidence or basis that would impel one of ordinary skill to pick the use of botulinum toxin to alleviate a burn pain, the Office Action has not established a *prima facie* case of obviousness. In deed, it is the Applicant who surprisingly discovered that a botulinum toxin may be administered to alleviate a burn pain.

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,

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